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MEETING MINUTES

Date: November 5, 1998 **Time:** 2:00 - 3:30 PM **Location:** WOCII, Conf. Rm. I
Topic: Docket number 98P-0311/CP1
External Participant: Wyeth-Ayerst Laboratories
FDA Lead: Janet Woodcock, M.D. **External Participant Lead:** Nancy L. Buc

FDA Participants:
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research (HFD-001)
Jane Axelrad, Associate Director for Policy (HFD-005)
Lisa Rarick, M.D., Director, Division of Reproductive and Urologic Drug Products (HFD-580)
Yuan-yuan Chiu, Ph.D., Deputy Director, Office of New Drug Chemistry (HFD-800)
Carol Drew, Regulatory Counsel (HFD-007)
David Horowitz, Attorney, Office of Chief Counsel (GCF-1)
Donna Katz, Attorney, Office of Chief Counsel (GCF-1)

External Participants:
Representing Wyeth-Ayerst Laboratories (W-A), Division of American Home Products Corporation (AHP):
Robert A. Essner, Executive Vice President, AHP
Joseph M. Mahady, President, W-A, North America
Marily H. Rhudy, Vice President, Public Affairs, AHP
Michael S. Dey, Ph.D., President, ESI Lederle
Heidi Hunter, Vice President, Women's Health Care, W-A
Michael P. Peskoe, Assistant General Counsel, Regulatory Affairs, AHP
Justin R. Victoria, Vice President Worldwide Regulatory Affairs, Wyeth-Ayerst
Donald O. Beers, Arnold and Porter
Nancy L. Buc, Buc and Beardsley
Jane E. Baluss, Buc and Beardsley

Meeting Objective:
To listen to Wyeth-Ayerst's reasoning in support of their citizen petition filed on May 12, 1998, docket number 98P-0311/CP1.

Background:
Wyeth-Ayerst requested a meeting in support of their citizen petition that FDA deny approval of any new drug application for a mixture of five of the estrogens found in Premarin.

Discussion:
The presentation tracked W-A's citizen petition and presented reasons why CDER should not approve a synthetic conjugated estrogens mixture. The reasons presented against approval covered primarily the points W-A raised in their citizen petition, including safety and effectiveness issues, the current USP monograph, naming issues, and marketing issues. They also

presented recent data concerning the progress of characterizing Premarin. At the end of their presentation there was an opportunity for FDA personnel to ask questions.

Nancy Bue began by making the following points:

- FDA should not look to the DESI notice on Premarin to approve a synthetic CE mixture.
- The manufacturer of any synthetic conjugated estrogens mixture should not be allowed to look to Premarin for safety and effectiveness data. (Ms. Bue referred to the July 1995 Advisory Committee memorandum and the May 5, 1997, CDER memorandum to support her arguments.)
- [redacted]
- It would be confusing/misleading to call any such synthetic product "conjugated estrogens".

Michael Dey, focusing on Wyeth-Ayerst's progress on the characterization of Premarin, provided the following information:

- [redacted]

- W-A had no clinical data on any of these newly found steroidal components individually or in some combination.
- Between 25 and 50 people are working on the characterization issue at any given time.

Mr. Dey also emphasized the inadequacy of the current USP monograph and stated W-A's position that the current monograph should be withdrawn or revised.

Decisions Reached:
No decisions were reached. After the presentations, Dr. Woodcock touched on the possibility of NIH becoming involved in clinical issues related to Premarin. One FDA attendee asked how long it would take to characterize Premarin, which W-A referred to as a multiyear process. At the conclusion of the meeting, Dr. Woodcock emphasized that all the materials Wyeth-Ayerst provided for the meeting and in their citizen petition would be considered in CDER's decision-making process.

Janet Woodcock, M.D.

cc: Attendees
R. Williams, M.D.
R. Hazzll
D. Moore
HFD-7/Petition File

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Reviewed and revised: CDrew, HFD-7: 12/14/98, 1/6/99
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Comments: JAreland, HFD-5: 12/22/98
Comments: LRarick, HFD-580: 11/19/98, 1/5/99

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